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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/503,089	02/11/2000	Amanda J. Patel	1030-R-00	6089

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 11/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/503,089	PATEL ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-16,18-20,22,23 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *23* is/are allowed.

6)☐ Claim(s) *13-16,18-20,22 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claim 13 has been amended. Claims 1-12, drawn to non-elected inventions, remain withdrawn from consideration. Claims 13-16, 18-20, 22 23 and 25 are under consideration.

2. After review and reconsideration, priority is granted only to the instant filing date for claims drawn to SEQ ID NO:2 and 4. Acknowledgement is made of applicants claim to priority via U.S. 6,309, 855, however '855 does not disclose SEQ ID NO:2, and further the instant SEQ ID NO:4 is also not present in '855. SEQ ID NO:8 of '855 has 99% homology to the first 368 amino acids of SEQ ID NO:4 and therefore fails to disclose the instant SEQ ID NO:4. Thus, claims 13-16 and 18-20 will be given the instant filing date as a priority date, but claims 22, 23 and 25 will be given the earlier priority date of September 1, 1998, based on the '855 patent.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

4. Claim 19 is objected to for the following formalities: the typographical errors of "nucleotidevector" and "siad". Appropriate correction is required.

5. Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 and 20 are vague and indefinite in the recitation of "said amino acid sequence" which lacks antecedent basis within each claim. Claims 19 and 20 are also vague and indefinite in the recitations of "nucleic acid molecule encoding (SEQ ID NO:2)" and "nucleic acid molecule encoding (SEQ ID NO:4)". It is unclear how SEQ ID NO:2 and 4 relate to the claims as the sequence identifiers are inserted within parentheses. for purpose of examination, the claims will be read without the parentheses.

6. Claims 18, 22 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

Claim 18 is drawn to a method dependent upon the identity of the TREK-1 protein. Claims 22 and 25 are method claims dependent upon the identity of the TASK protein. The TREK-1 and the TASK proteins of the claims encompass a genus of proteins which exhibit outward-going potassium rectification. The genus is not limited by structural limitations and therefore encompasses proteins that differ substantially in structure for SEQ ID NO:2 and 4, in the case of TREK-1 and SEQ ID NO:5 in the case of TASK. The specification states that the sequence of TREK-1 may be any amino acid sequence that is substantially identical to TREK-1. The specification does not define the limits of what is substantially identical to TREK-1 versus not substantially identical to TREK-1. Thus, the recitation of TREK-1 reads on any number of structural alterations and variants of TREK-1 that have not been disclosed. The disclosure of SEQ ID NO:2 and 4 does not describe the genus of TREK-1, nor does the disclosure of SEQ ID NO:5 describe the genus of TRAK because the genus includes numerous structural variants which differ from SEQ ID NO:2, 4 and 5. Thus, the specification lacks adequate written description for a genus of TREK-1 and a genus of TRAK. It Claims drawn to a method of using a product cannot be adequately described if the product itself has not been adequately described. Therefore, one of skill in the art would reasonably conclude that applicant was not in possession of the claimed genus upon which the method claims depend.

7. Claims 13-16, 18-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Patel et al (Nature Neuroscience, 1999, Vol. 2, pp. 422-426).

Claim 13 is drawn to a method for identifying substances having anesthetic properties, wherein said substances produce a reversible state of consciousness with amnesia and analgesia in a mammal upon inhalation, said method comprising contacting said substances with TREK-1 or TASK or variants of TREK-1 or TASK having at least 95% sequence identity to SEQ ID NO:2 , 4 or 5, wherein SEQ ID NO:2, 4 or 5 are mammalian transport proteins which exhibit outward-going potassium rectification, and determining the potassium transport of said TREK-1 or TASK protein wherein an activation of potassium transport activity is indicative that said

substance has anesthetic properties. Claims 14 and 15 embody the method of claim 13 wherein said potassium transport proteins is TASK or TREK-1 , respectively. Claim 16 embodies the method of claim 15 wherein said TREK-1 comprises either SEQ ID NO:2 or SEQ ID NO:4. Claim 18 is drawn to a method for identifying substances having anesthetic properties wherein said substance produce a reversible state of consciousness with concurrent amnesia and analgesia upon inhalation be a mammal comprising contacting said substance with COS cells wherein said COS cells are transfected with a nucleotide vector comprising a nucleic acid molecule encoding TREK-1 wherein said COS cells transiently express said TREK-1 and wherein said TREK-1 exhibits outward going potassium rectification; and determining the potassium transport activity of said TREK-1 wherein an activation of potassium transport is indicative of said substance having anesthetic properties. Claim 19 is drawn to a method for identifying substances having anesthetic properties wherein said substance produce a reversible state of consciousness with concurrent amnesia and analgesia upon inhalation be a mammal comprising contacting said substance with COS cells wherein said COS cells are transfected with a nucleotide vector comprising SEQ ID NO:2, wherein said COS cells transiently express the protein encoded by SEQ ID NO:2 and wherein said protein exhibits outward going potassium rectification; and determining the potassium transport activity of said protein wherein an activation of potassium transport is indicative of said substance having anesthetic properties. Claim 20 is drawn to a method of identifying substances having anesthetic properties wherein said substance produce a reversible state of consciousness with concurrent amnesia and analgesia upon inhalation be a mammal comprising contacting said substance with COS cells wherein said COS cells are transfected with a nucleotide vector comprising SEQ ID NO:4, wherein said COS cells transiently express the protein encoded by SEQ ID NO:4 and wherein said protein exhibits outward going potassium rectification; and determining the potassium transport activity of said protein wherein an activation of potassium transport is indicative of said substance having anesthetic properties.

Patel et al disclose a method for identifying substances having anorthic properties upon inhalation comprising contacting said substance with TREK-1 (mouse and human) or TASK expressed on the surface of COS cells (pages 422-425, under "Results"). It is noted that human TREK-1 is SEQ ID NO:2 and mouse TREK-1 is SEQ ID NO:4 and that activation of potassium

transport in the TREK-1 or TASK proteins was observed by outward-going potassium rectification (page 423, second column, lines 3-6).

8. Claims 13-16, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franks and Lieb (Nature, 1988, vol. 333, pp. 662-664, cited in a previous Office action) in view of Patel et al (EMBO, 1998, Vol. 17, pp. 4283-4289, reference AN of the IDS filed February 11, 2000). the specific embodiments of the claims are recited above.

Franks and Lieb teach a direct correlation between the presence of an anesthetic-induced current, Ik(an) and anesthetic-induced inhibition of spontaneous firing in a given neurons and that those neurons which were insensitive to anesthesia lacked the Ik(an) current while said current was always present in a sensitive cell. Franks and Leib teach that such anesthesia activated potassium channels have just the properties that might be expected for the principle target sites involved in general anesthesia (page 664, first column, lines 34-36).

Patel et al teach that TREK-1 encodes a mammalian mechano-activated potassium channel which shares most of the properties of the Aplysia S-type potassium channel (page 4283, second column, last 4 lines). Patel et al compare the opening of the TREK-1 potassium channel by chloroform with the opening of the Aplysia channel by chloroform (page 4286, bridging paragraph and legend for Figure 1). Patel et al especially note that the I-V curve of the chloroform activated current in TREK-1 is identical to the AA-sensitive current. Further both the Aplysia S channel and the TREK-1 channel are both mechano-activated (page 4285, second column, lines 16-21). It is noted that Patel et al teach mouse TREK-1 which is SEQ ID NO:4.

It would have been prima facie obvious to one of skill in the art at the time the invention was filed to substitute the measurement of the Ik(an) current in TREK-1 for the measurement of the Ik(an) current of the Aplysia-S channel. One of skill in the art would be motivated to do so by the teachings of Patel et al on the similarities between the current induced by anesthesia in the TREK-1 potassium channel and the current induced by the Aplysia S channel in response to general anesthetics. One of skill in the art would be motivated to identify substances having the property of inducing said Ik(an) current by the teachings of Franks and Lieb on the targeting of said current by general anesthesias and additionally because the mammalian homolog of the Aplysia S-channel would be more appropriate in the screening of said substances, as one of skill

in the art would recognize that said substance would the have the potential of being used clinically to induce reversible unconsciousness in a mammalian subject.

9. All other rejections and objections as set forth in Paper no. 21 are withdrawn

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
11/03/03